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(54) WOUND DRESSING

WUNDVERBAND

PANSEMENT POUR PLAIES

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Description

Field of the Invention

[0001] The present invention relates to a flexible sheet material for covering wounds. The flexible sheet material includes an antimicrobial agent.

Background of the Invention

[0002] Various materials are commonly used to cover a wound while the wound heals. These materials provide a protective layer over the wound, facilitating healing in a moist environment while acting as a barrier to liquids and microorganisms.

[0003] In typical wound dressings, an absorbant material is held in place over the wound by a piece of tape. The absorbant material may or may not comprise a medicament. A typical wound dressing in which the absorbant material comprises a medicament is disclosed in U.S.-A-4,728,323 (Matson). These antimicrobial wound dressings are prepared by vapor coating or sputter etching certain silver salts onto a variety of wound dressing substrates.

[0004] Alternatively, the wound dressing may comprise a film or tape wherein a substantial portion of the film or tape is covered by an adhesive with an antimicrobial agent dispersed throughout or complexed to the adhesive. Such wound dressings are disclosed in U. S-A-4,310,509 (Berglund, et al.) and U.S.-A- 4,323,557 (Rosso, et al.), respectively.

[0005] US-A-5238685 discloses a flexible sheet material having a plurality of edges and comprising a backing and a dermatologically acceptable pressure-sensitive adhesive covering at last a portion of said backing and for adhering said sheet material to the skin. The sheet material includes a first region having a first surface opposite to said backing adapted for contact with a wound and for facilitating cell regeneration of the wound area and a second region surrounding said first region and having a second surface opposite said backing, said second region comprising an antimicrobial agent at least sufficient to prevent migration of microorganism to said first region from the external environment along the interface between said sheet material and skin to which said sheet material has been adhered.

Summary of the Invention

[0006] The present invention provides a flexible sheet material having a plurality of edges and comprising a backing and a dermatologically acceptable pressure-sensitive adhesive covering at least a portion of the backing and for adhering the sheet material to skin, the sheet material being defined by

a) a first region having a first surface opposite said backing adapted for contact with a wound and for facilitating cell regeneration in and therefore healing of said wound, said first region being removed from said edges of said flexible sheet material; and

b) a second region substantially surrounding said first region and having a second surface opposite said backing, said second region comprising an antimicrobial agent available at said second surface in an amount which is greater than that which facilitates wound cell regeneration and is at least sufficient to inhibit or essentially prevent migration of microorganisms to said first region from the external environment along the Interface between said sheet material and skin to which said sheet material has been adhered; and further comprising

c) an intermediate region between said first region and said second region and separating said first region from said second region, wherein said intermediate region optionally comprises an antimicrobial agent, with the proviso that if the antimicrobial agent In said intermediate region is the same as that In the second region, then said antimicrobial agent is present in said intermediate region at a lower concentration than that of said second region.

[0007] Preferred embodiments of the invention become apparent from the dependent claims.

[0008] The first region preferably comprises cell growth-enhancing agents. The first region also preferably provides a void space for wound exudate. A wound often secretes fluids during the healing process, and this void space provides an area into which the wound exudate may flow.

[0009] The flexible sheet material of the invention additionally includes an intermediate region between the first and second regions. This intermediate region may simply comprise the uncoated backing of the flexible sheet material. Alternatively, a dermatologically acceptable pressure sensitive adhesive may be applied to the backing in the intermediate region, and this adhesive may or may not comprise an antimicrobial agent or a medicament of some type. If this intermediate region comprises the same antimicrobial agent as is in the second region, this antimicrobial agent will be present at a lower concentration than that of the second region.

Brief Description of the Drawings

[0010] The invention will be more fully explained with reference to the following drawings in which:

Figure 1 is a top plan view of an embodiment not according to the invention.

Figure 2 is a top plan view of an embodiment of the invention.

Figure 3 is a partial breakaway view of an embodiment not according to the invention.

[0011] These figures, which are idealized, are not to

scale and are intended to be merely illustrative and non-limiting.

Detailed Description of Preferred Embodiments

[0012] Wound dressing 10 comprises backing 16, pressure-sensitive adhesive layer 14 coated on a portion of backing 16, and an absorbant web or other material 12 to provide a void space for wound exudate. The absorbant web or other material 12 is adhered to backing 16 by means of an adhesive which may or may not be an extension of adhesive layer 14. Adhesive layer 14 comprises an antimicrobial agent which is available at the surface of adhesive layer 14 to inhibit or essentially prevent migration of microorganisms from the external environment to web 12.

[0013] The first region of wound dressing 10 comprises web 12, and the portions of any adhesive layer and backing 16 directly underlying web 12. The exposed surface of web 12 is considered to be the first surface of the first region as defined in the instant claims.

[0014] The second region of wound dressing 10 comprises the portions of the adhesive layer 14 and backing 16 extending beyond and not underlying web 12. The exposed surface of adhesive layer 14 is considered to be the first surface of the second region as defined in the instant claims.

[0015] It may be desirable to include a barrier layer to inhibit or prevent any antimicrobial contained in the adhesive layer underlying web or other material 12 from migrating to the exposed surface of web or other material 12. Typically, the barrier, which is positioned between web or other material 12 and the underlying adhesive layer, comprises a polymeric film on the order of 5 to 10 micrometers which is substantially impermeable to the antimicrobial agent.

[0016] Figure 2 illustrates a top plan view of an embodiment 10' of the invention further comprising intermediate region 18.

[0017] Figure 3 depicts a partial breakaway view of an embodiment 10" not according to the invention. In this embodiment, second region 14 extends to the outer edge of the flexible sheet material.

[0018] The backing 16 is preferably flexible, yet possesses sufficient structural integrity to provide a durable wound dressing. The backing should not cause or contribute to the degradation of the adhesive. The backing is preferably permeable to air and moisture vapor. The backing is also preferably substantially impermeable to liquids and microorganisms.

[0019] Examples of suitable materials for backing include, but are not limited to, polyurethanes, polyesters, and vinyls. The preferred thickness of the backing will depend on which material is used and whether the backing is a solid film or a foam. Typical thicknesses range from 10 micrometers for a thin film backing to 800 micrometers for a foam backing.

[0020] The pressure sensitive adhesive used in the wound dressing of the invention should adhere well to skin, and be dermatologically acceptable. Additionally, the adhesive should be such as to allow the antimicrobial agent to be added thereto, without causing degradation of the antimicrobial agent. Typical adhesives used in the flexible sheet material of the invention may include, but are not limited to, acrylate adhesives, rubber-based adhesives, and silicone-based adhesives.

[0021] The combination of adhesive and backing should have a moisture vapor transmission rate of at least 300 grams/m^2/24 hours, and more preferably a moisture vapor transmission rate of at least 500 grams/m^2/24 hours.

[0022] The absorbant web or other material 12 present in the first region of the wound dressing preferably includes a material with substantial void space. Such a void space provides an area for the wound exudate to flow into. Examples of suitable materials include but are not limited to fibers of cotton, rayon, or other cellulosic materials, polyolefins, polyesters, and combinations thereof.

[0023] Additionally, absorbant web or other material 12 preferably comprises a mild antimicrobial, and/or cell growth enhancing agents, and/or other medicaments. Any antimicrobial agent present in the absorbant web or other material 12 is typically a mild antimicrobial, or the same antimicrobial agent as is in the second region but at a much lower concentration. Any antimicrobial and amount thereof selected for inclusion in absorbant web or other material 12 should be compatible for direct contact with a wound. Examples of other medicaments suitable for use in the absorbant web or other material 12 include but are not limited to fungicides, anti-acne agents, antioxidants, antibiotics, and cosmetic astringents.

[0024] Antimicrobial agents which may be present in pressure-sensitive adhesive layer 14 in the second region of wound dressing 10 include cosmetic biocides. Examples of suitable antimicrobial agents include but are not limited to iodine, hydrogen peroxide, benalkonium chloride, and aluminum chlorohydrate. One of ordinary skill in the art will readily be able to select an appropriate amount of the selected antimicrobial for inclusion in adhesive layer 14.

Reference-Examples

Example 1

[0025] A strip of 2.5 x 7.6 cm Microfoam™ Tape commercially available from 3M was cut. Then a 0.3 cm wide band of loban™ 2 6650 Antimicrobial Film commercially available from 3M was cut and applied to the outside edge of the adhesive on the Microfoam™ Tape. The liner was removed to expose the adhesive surface of the antimicrobial film. Then a 1.9 x 2.5 cm piece of 125.45 g/m^2, 90/10 poly propylene/rayon blend single side laminated with 530 P™ high density polyethylene netting

(the entire construction commercially available from Applied Extrusion Technologies (AET), Middletown, DE) was placed in the center of the adhesive side of the Microfoam™ Tape. A solution of Benzalkonium Chloride (BTC 50 USP) commercially available from Stepan Company, Northfield, IL (0.13% wt/wt in Ethanol/water) was added to the pad to a concentration of 0.13 wt/wt%.

Example 2

[0026] A strip of 4 x 10 cm piece of melt blown polyurethane tape commercially available from Medical Specialties Division of 3M Company may be cut. A 1 cm wide ring of PVP-Iodine™ 30/06 commercially available from BASF Corporation, Parsippany, NJ (10% wt/wt in Ethanol) is then painted onto the adhesive side of the strip of melt blown polyurethane tape using a cotton swab. The ring is placed 0.6 cm inside of the outer perimeter of the piece of melt blown polyurethane tape. A 1 x 4 cm piece of 530 P™ high density polyethylene netting commercially available from Applied Extrusion Technologies (AET), Middletown, DE, that was vapor coated with silver chloride according to U.S.-A-4,728,323 is then placed inside the ring of PVP-Iodine at the center of the adhesive side of the piece of melt blown polyurethane tape.

Example 3

[0027] A 6.3 x 8.3 cm piece of Tegaderm™ HP Transparent Dressing commercially available from 3M was cut. Then a 1 cm ring of PVP stabilized Peroxide (PVP/02-1™) solution commercially available from ISP Technologies, Inc., Wayne, NJ (5% wt/wt in Ethanol) was painted on using a cotton swab to the adhesive side of the tape. The ring was placed 0.6 cm inside the outer perimeter of the tape. A'2.5 x 2.5 cm pad of melt blown polypropylene was placed in the center of the adhesive side of the Tegaderm™ HP Transparent Dressing. A solution of Benzalkonium Chloride (BTC 50 USP) commercially available from Stepan Company, Northfield, IL (0.13% wt/wt in Ethanol/water) was added to the pad to a concentration of 0.13 wt/wt%.

Example 4

[0028] A 3 x 9 cm piece of Ioban™ 2 6650 Antimicrobial Film commercially available from 3M was cut. Then a 1.3 x 3.8 cm piece of 108.5 g/m^2, rayon double side laminated with 530 P high density polyethylene netting (the entire construction commercially available from Applied Extrusion Technologies (AET), Middletown, DE) was placed in the center of the adhesive side of the antimicrobial film. A solution of Benzalkonium Chloride (BTC 50 USP) commercially available from Stepan Company, Northfield, IL (0.13% wt/wt in Ethanol/water) was added to the pad to a concentration of 0.13 wt/wt%.

Example 5

[0029] A 3 x 9 cm piece of Ioban™ 2 6650 Antimicrobial Film commercially available from 3M was cut. Then a 1.3 x 3.8 cm piece of 108.5 g/m^2, rayon double side laminated with 530 P high density polyethylene netting (the entire construction commercially available from Applied Extrusion Technologies (AET), Middletown, DE), was placed in the center of the adhesive side of the antimicrobial film. A solution of PVP-Iodine™ 30/06 commercially available from BASF Corporation, Parsippany, NJ (10% wt/wt in Ethanol) was added to the pad to a concentration of 10 wt/wt%.

Example 6

[0030] A 3 x 9 cm piece of Tegaderm™ Dressing commercially available from 3M was cut. Then a 1.3 x 3.8 cm piece of 108.5 g/m^2, rayon double side laminated with 530 P™ high density polyethylene netting (the entire construction commercially available from Applied Extrusion Technologies (AET), Middletown, DE) was placed in the center of the adhesive side of the Tegaderm™ Dressing. Then a 1 cm ring of PVP Stabilized Peroxide (PVP/02-1™) solution commercially available from ISP Technologies, Inc., Wayne, NJ (5% wt/wt in Ethanol) was painted on using a cotton swab to the adhesive side of the tape. The ring was around the perimeter of the pad. A solution of Benzalkonium Chloride (BTC 50 USP) commercially available from Stepan Company, Northfield, IL (0.13% wt/wt in Ethanol/water) was added to the pad to a concentration of 0.13 wt/wt%.

Example 7

[0031] A 3 x 9 cm piece of Tegaderm™ Dressing commercially available from 3M was cut. Then a 1.3 x 3.8 cm piece of 108.5 g/m^2, rayon double side laminated with 530 P™ high density polyethylene netting (the entire construction commercially available from Applied Extrusion Technologies (AET), Middletown, DE), was placed in the center of the adhesive side of the Tegaderm™ Dressing. Then a 1 cm ring of PVP Stabilized Peroxide (PVP/02-1™) solution commercially available from ISP Technologies, Inc., Wayne, NJ (5% wt/wt in Ethanol) was painted on using a cotton swab to the adhesive side of the tape. The ring was around the perimeter of the pad. A solution of PVP-Iodine™ 30/06 commercially available from BASF Corporation, Parsippany, NJ (10% wt/wt in Ethanol) was added to the pad to a concentration of 10 wt/wt%.

Claims

1. A flexible sheet material (10) having a plurality of edges and comprising a backing (16) and a dermatologically acceptable pressure-sensitive adhesive

covering at least a portion of said backing (16) and for adhering said sheet material to skin, said sheet material being defined by :

a) a first region (12, 16) having a first surface opposite said backing (16) adapted for contact with a wound and for facilitating cell regeneration in and therefore healing of said wound, said first region being removed from said edges of said flexible sheet material (10); and
b) a second region (14, 16) substantially surrounding said first region (12, 16) and having a second surface opposite said backing (16), said second region (14, 16) comprising an antimicrobial agent available at said second surface in an amount which is greater than that which facilitates wound cell regeneration and is at least sufficient to inhibit or essentially prevent migration of microorganisms to said first region (12, 16) from the external environment along the interface between said sheet material and skin to which said sheet material has been adhered; and further comprising
c) an intermediate region (18) between said first region (12, 16) and said second region and separating said first region (12, 16) from said second region (14, 16), wherein said intermediate region (18) optionally comprises an antimicrobial agent, with the proviso that if the antimicrobial agent in said intermediate region (18) is the same as that in the second region (14, 16), then said antimicrobial agent is present in said intermediate region (18) at a lower concentration than that of said second region (14, 16).

2. The flexible sheet material of claim 1, wherein said first region (12, 16) includes a material providing a void space for wound exudate.

3. The flexible sheet material of claim 1, wherein said first surface of said first region (12, 16) is substantially free of said antimicrobial agent contained in said second region.

4. The flexible sheet material of claim 1, wherein said first region (12, 16) and said second region (14, 16) are substantially. concentric.

5. The flexible sheet material of claim 1, wherein said intermediate region (18) is substantially free of said antimicrobial agent contained in said second region (14, 16).

6. The flexible sheet material of claim 1, wherein said second region (14, 16) extends to said edges of said flexible sheet material (10).

7. The flexible sheet material of claim 2, wherein said first region (12, 16) comprises at least one agent compatible for direct wound contact.

8. The flexible sheet material of claim 1, wherein said second region comprises a pressure-sensitive adhesive comprising said antimicrobial agent dispersed throughout or complexed to said adhesive.

9. The flexible sheet material of claim 1, wherein the combination of said backing and said pressure sensitive adhesive exhibit a moisture vapor transmission rate greater than 300 gms/m^2/24 hour moisture vapor transmission rate.

10. The flexible sheet material of claim 1, wherein said backing (16) is substantially impermeable to microorganisms, but is substantially permeable to moisture vapor.

11. The flexible sheet material of claim 1, wherein said first region (12, 16) comprises an absorbant material.

Patentansprüche

1. Flexibles, dünnes flächiges Material (10), das eine Mehrzahl von Kanten aufweist und eine Unterlage (16) und einen dermatologisch annehmbaren Haftkleber umfasst, der wenigstens einen Teil der Unterlage (16) bedeckt und das dünne flächige Material an die Haut kleben soll, wobei das dünne flächige Material durch folgendes definiert ist:

a) einen ersten Bereich (12,16) mit einer ersten Oberfläche, welche der Unterlage (16) gegenüberliegt, der für den Kontakt mit einer Wunde befähigt ist und zur Erleichterung der Zellenregenerierung in der Wunde und daher zum Heilen der Wunde befähigt ist, wobei der erste Bereich von den Kanten des flexiblen, dünnen flächigen Materials (10) entfernt wird; und
b) einen zweiten Bereich (14,16), der im Wesentlichen den ersten Bereich (12,16) umgibt und eine zweite Oberfläche aufweist, welche der Unterlage (16) gegenüberliegt, wobei der zweite Bereich (14,16) einen antimikrobiellen Wirkstoff umfasst, der auf der zweiten Oberfläche in einer Menge verfügbar ist, die größer ist als diejenige, welche eine Zellenregenerierung der Wunde erleichtert, und die wenigstens ausreichend ist, um eine Wanderung von Mikroorganismen in den ersten Bereich (12,16) von der äußeren Umgebung her entlang der Grenzfläche zwischen dem dünnen flächigen Material und der Haut, an die das dünne flächige Material geklebt wurde, zu hemmen oder im Wesentlichen zu verhindern; und weiterhin umfas-

send
c) einen intermediären Bereich (18) zwischen dem ersten Bereich (12,16) und dem zweiten Bereich (14,16), der den ersten Bereich (12,16) von dem zweiten Bereich (14,16) trennt, wobei der intermediäre Bereich (18) gegebenenfalls einen antrmikrobiellen Wirkstoff umfasst, mit der Maßgabe, dass, wenn der antimikrobielle Wirkstoff in dem intermediären Bereich (18) mit demjenigen in dem zweiten Bereich (14,16) identisch ist, dann der antimikrobielle Wirkstoff in dem intermediären Bereich (18) in einer geringeren Konzentration vorliegt als derjenigen des zweiten Bereichs (14,16).

2. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der erste Bereich (12,16) ein Material einschließt, das einen Hohlraum für ein Exsudat der Wunde bereitstellt.

3. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei die erste Oberfläche des ersten Bereichs (12,16) im Wesentlichen frei von dem antimikrobiellen Wirkstoff ist, der in dem zweiten Bereich enthalten ist.

4. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der erste Bereich (12,16) und der zweite Bereich (14,16) im Wesentlichen konzentrisch sind.

5. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der intermediäre Bereich (18) im Wesentlichen frei von dem antimikrobiellen Wirkstoff ist, der in dem zweiten Bereich (14,16) enthalten ist.

6. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der zweite Bereich (14,16) sich bis zu den Kanten des flexiblen, dünnen flächigen Materials (10) erstreckt.

7. Flexibles, dünnes flächiges Material gemäß Anspruch 2, wobei der erste Bereich (12,16) wenigstens ein Mittel umfasst, das für einen direkten Kontakt mit der Wunde verträglich ist.

8. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der zweite Bereich einen Haftkleber umfasst, der den antimikrobiellen Wirkstoff umfasst, der überall in dem Klebstoff fein verteilt oder komplexiert ist.

9. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei die Kombination von Unterlage und Haftkleber eine Feuchtigkeitsdampf-Durchlässigkeitsrate von größer als 300 g/m^2 pro 24 h aufweist.

10. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei die Unterlage (16) gegenüber Mikroorganismen im Wesentlichen undurchlässig ist, gegenüber Feuchtigkeitsdampf aber im Wesentlichen durchlässig ist.

11. Flexibles, dünnes flächiges Material gemäß Anspruch 1, wobei der erste Bereich (12,16) ein Absorptionsmaterial umfasst.

Revendications

1. Matériau en feuille souple (10) ayant une pluralité de bords, et comportant un renfort (16) et un adhésif sensible à la pression acceptable dermatologiquement recouvrant au moins une partie dudit renfort (16), et destiné à mettre en adhérence ledit matériau en feuille sur la peau, ledit matériau en feuille étant défini par :

   a) une première zone (12, 16) ayant une première surface opposée audit renfort (16) adaptée pour venir en contact avec plaie, et destinée à faciliter la régénération de cellules dans la plaie, et par conséquent la guérison de celle-ci, ladite première zone étant enlevée desdits bords dudit matériau en feuille souple (10), et
   b) une seconde zone (14, 16) entourant sensiblement ladite première zone (12, 16) et ayant une seconde surface opposée audit renfort (16), ladite seconde zone (14, 16) comportant un agent antimicrobien disponible au niveau de ladite seconde surface en une quantité qui est supérieure à celle qui facilite la régénération de cellules de plaie, et qui est au moins suffisante pour empêcher ou gêner sensiblement la migration de micro-organismes vers ladite première zone (12, 16) à partir de l'environnement extérieur le long de l'interface entre ledit matériau en feuille et la peau sur laquelle ledit matériau de feuille a été mis en adhérence, et comportant de plus
   c) une zone intermédiaire (18) située entre ladite première zone (12, 16) et ladite seconde zone (14, 16), et séparant ladite première zone (12, 16) et ladite seconde zone (14, 16), ladite zone intermédiaire (18) comportant facultativement un agent antimicrobien, la condition étant que si l'agent antimicrobien situé dans ladite zone intermédiaire (18) est le même que celui situé dans la seconde zone (14, 16), alors ledit agent antimicrobien est présent dans ladite zone intermédiaire (18) à une concentration plus basse que celle de ladite seconde zone (14, 16).

2. Matériau en feuille souple selon la revendication 1,

dans lequel ladite première zone (12, 16) comporte un matériau fournissant un espace vide pour un exsudat de plaie.

3. Matériau en feuille souple selon la revendication 1, dans lequel ladite première surface de ladite première zone (12, 16) est sensiblement dépourvue dudit agent antimicrobien contenu dans ladite seconde zone.

4. Matériau en feuille souple selon la revendication 1, dans lequel ladite première zone (12, 16) et ladite seconde zone (14, 16) sont sensiblement concentriques.

5. Matériau en feuille souple selon la revendication 1, dans lequel ladite zone intermédiaire (18) est sensiblement dépourvue d'agent antimicrobien contenu dans ladite seconde zone (14, 16).

6. Matériau en feuille souple selon la revendication 1, dans lequel ladite seconde zone (14, 16) s'étend vers lesdits bords dudit matériau en feuille souple (10).

7. Matériau en feuille souple selon la revendication 2, dans lequel ladite première zone (12, 16) comporte au moins un agent compatible destiné à être en contact direct avec la plaie.

8. Matériau en feuille souple selon la revendication 1, dans lequel ladite seconde zone comporte un adhésif sensible à la pression comportant ledit agent antimicrobien dispersé d'un bout à l'autre dudit adhésif, ou complexé à celui-ci.

9. Matériau en feuille souple selon la revendication 1, dans lequel la combinaison dudit renfort et dudit adhésif sensible à la pression présente un débit de transmission de vapeur d'humidité supérieur à un débit de transmission de vapeur d'humidité de 300 $gm/m^2/24$ heures.

10. Matériau en feuille souple selon la revendication 1, dans lequel ledit renfort (16) est sensiblement imperméable aux micro-organismes, mais est sensiblement perméable à la vapeur d'humidité.

11. Matériau en feuille souple selon la revendication 1, dans lequel ladite première zone (12, 16) comporte un matériau absorbant.

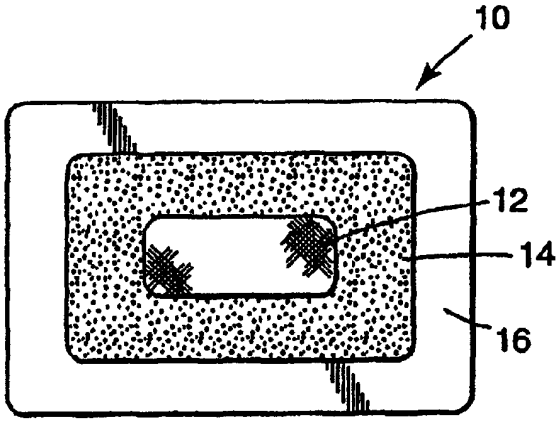

Fig.1

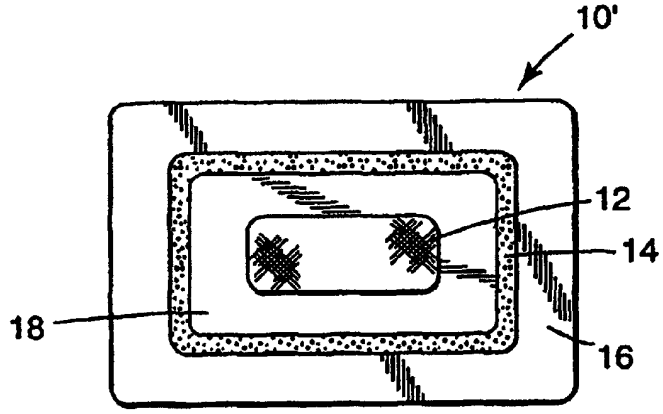

Fig.2

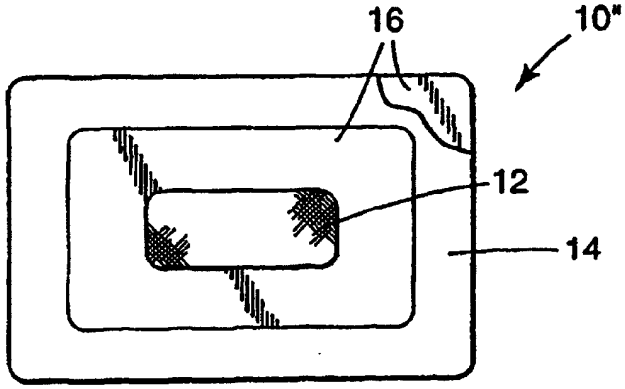

Fig.3